

## REMARKS

Claims 1-4 and 6-11 stand rejected and are presently pending in the application. Favorable reconsideration in view of the following remarks is earnestly solicited.

### **Rejection under 35 U.S.C. § 103(a) over Asgharian et al.:**

The Office Action dated June 29, 2010 rejects claims 1-4 and 6-11 under 35 U.S.C. § 103(a) as being unpatentable over Asgharian et al. (U.S. 6,139,646) indicating that Asgharian et al. teaches the use of a simple saccharide in a composition that contains PHMB. In light of the following remarks and the previously submitted declaration of Mr. Ed Jahngen, it is respectfully requested that this rejection be reconsidered and withdrawn.

The instant claims relate to an ophthalmic solution and a method of applying the solution in which the solution is physiologically compatible with direct contact with corneal eye tissue. When utilizing a solution that comes in direct contact with the eye, it is important to ensure that none of the components of the solution would provide any adverse effects. When determining the patentability of the claims, the invention must be viewed as whole. "[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103." *In re Spinnoble*, 405 F.2d 578, 585 (CCPA 1969).

Enzyme solutions, such as those taught by Asgharian et al., are often used to digest protein build up on contact lenses. The enzymes digest the protein and therefore remove the build up on the lens. However, enzyme solutions would be detrimental if they came in direct contact with the eye. The enzyme would digest the proteins naturally found in the eye causing severe adverse effects. Therefore, it is important to properly rinse and then disinfect contact lenses after using an enzyme solution prior to returning the contact lens to the eye.

The Examiner has indicated that the arguments and declaration have been considered, but are not deemed to be persuasive. When an applicant submits evidence, in reply to a rejection, the examiner must reconsider the patentability of the claimed

invention. The decision on patentability must be made based upon consideration of all the evidence. A decision to make or maintain a rejection in the face of all the evidence must show that it was based on the totality of the evidence. Facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion of obviousness was reached, not against the conclusion itself. *In re Eli Lilly & Co.*, 902 F.2d 943 (Fed. Cir. 1990).

In reviewing a reference, it is required that the reference be viewed as a whole. The totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. *In re Hedges*, 783 F.2d 1038 (Fed. Cir. 1986). Asgharian et al. relates, as a whole, to an enzyme solution. This is evidenced by the claims, examples, specification and abstract. Each claim recites a solution containing alkyl trypsin to produce an enzyme solution. Furthermore, the examples all relate to forming either a multi-purpose composition, or a two-part composition, both containing an enzyme for the digestion of proteins. Even the abstract discloses that the reference is directed to a liquid enzyme composition for cleaning a contact lens. When reading Asgharian et al. as a whole, the reference is directed towards enzyme solutions.

Reading Asgharian et al. as a whole, the teachings are related to a liquid enzyme composition (abstract) for cleaning a contact lens. However, this enzyme composition would not be suitable for direct eye contact as enzyme solutions are known to those skilled in the art to be harmful to the eye. Applicant kindly directs the Examiner's attention to Exhibit 1 of the response filed April 12, 2010, the declaration of Mr. Ed Jahngen, filed under 37 C.F.R. §132 ("Declaration"), indicating that enzyme solutions, such as those disclosed by Asgharian et al. are not suitable for in-eye applications. Declaration, Para. 9. The Declaration indicates that enzyme solutions are used to digest protein build up on contact lenses, and if the enzyme solution were to come in direct contact with the eye the solution would digest the proteins naturally found in the eye thereby causing adverse effects. Declaration, Paras 5 – 6. A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983).

Regarding the indication that Asgharian et al. teaches a solution that is suitable for direct contact with corneal tissue, Col. 9, Lns. 61 – 63 indicate that the multi-purpose composition is intended to function as storing, rinsing, cleaning and disinfecting solutions. Asgharian et al. is silent regarding direct contact with corneal tissue. Because of the dangers of enzyme solutions, it is imperative to rinse any remaining enzyme solution away from a contact lens prior to placing the lens in contact with an eye. Declaration, Para. 7. Although enzyme solutions, such as those disclosed by Asgharian et al., may be physiologically compatible as storing, rinsing, cleaning and disinfecting solutions, enzyme solutions are not suitable for direct contact with corneal tissue as claimed. It is understood that even in the applied functions of storing, rinsing, cleaning and disinfecting, such enzyme solutions would be rinsed away prior to placing a contact lens in contact with an eye to prevent the enzyme from digesting the healthy proteins naturally found in the eye.

It is well established that "[k]nown disadvantages in old devices which would naturally discourage search for new inventions may be taken into account in determining obviousness." *United States v. Adams*, 383 U.S. 39, 52 (1966). Based on the evidence previously submitted, it is clear that enzyme solutions are not suitable for direct contact with the eye. In viewing Asgharian et al. as a whole, the reference is directed to enzyme based solutions.

As the instant claims recite a solution that is physiologically compatible with direct contact with corneal tissue, and, as evidenced by the Declaration, enzyme solutions are not suitable for in-eye applications, it is respectfully requested that this rejection be withdrawn.

**Conclusion:**

Applicant respectfully submits that Claims 1, 11, 17 and all claims that depend therefrom are therefore in condition for allowance.

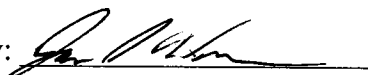
Applicant appreciates the opportunity to call the Examiner but believes that the forgoing remarks fully address the issues raised by the Examiner. On the other hand, the Examiner is invited to call the undersigned attorney if he has any matters to address that will facilitate allowance of the application.

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Resp. Dated November 29, 2010  
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In the event that Applicant has overlooked the need for an extension of time, additional extension of time, payment of fee, or additional payment of fee, Applicant hereby conditionally petitions therefore and authorizes that any changes be made to Deposit Account No.: 50-3010.

Respectfully submitted,

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